BEFORE THE UNITED STATES
ENVIRONMENTAL PROTECTION AGENCY
OFFICE OF PESTICIDE PROGRAMS

RESPONSE BY CUPRON, INC., AND EOS SURFACES, LLC, TO THE PETITION BY THE COPPER DEVELOPMENT ASSOCIATION INC. TO CANCEL THE ANTIMICROBIAL CUPRON ENHANCED EOS SURFACE, EPA REGISTRATION NUMBER 84542-7

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I. INTRODUCTION

The Office of Pesticide Programs (OPP) of the U.S. Environmental Protection Agency (EPA) recently decided to construe two submissions by the Copper Development Association Inc. (CDA), one made on November 2, 2012,[1] and one made on May 28, 2013,[2] as a petition to cancel the Antimicrobial Cupron Enhanced EOS Surface (EOS Surface), EPA Reg. No. 84542-7,[3] a pesticide registered under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). EPA has afforded the registrant, Cupron, Inc. (Cupron), an opportunity to respond to the allegations in the CDA submissions at issue, and this submission constitutes the response of Cupron and its affiliate EOS Surfaces, LLC (EOS).

Although it is not addressed by CDA, the commercial context in which the CDA allegations are made is a critically important component of the allegations. EOS Surface directly competes in certain markets with antimicrobial copper alloy surface products registered by CDA members. EOS Surface has been successfully deployed in a number of medical care and other institutional environments, and this success in the marketplace may be perceived as a competitive threat by the registrants of copper alloy products. This is especially the case because

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1 Letter from Andrew G. Kireta, CDA President, to Joan Harrigan-Farrelly, Director, Antimicrobials Division, OPP (Nov. 2, 2012) (CDA Submission).

2 Letter from Andrew G. Kireta, CDA President, to Susan Lewis, Director, Antimicrobials Division, OPP (May 28, 2013), attaching Non-GLP Study Report, "Test Method for determining the Efficacy of Antimicrobial Surfaces as Sanitizers," test by ATS Labs sponsored by CDA (May 1, 2013) (CDA Study).

3 Letter from John Hebert, Chief, Regulatory Management Branch I, Antimicrobials Division, OPP, to Cupron, Inc. (Sept. 25, 2014).

the durable nature of these products and the protracted period they will be in service makes a decision by any prospective customer to select a particular copper-containing surface product one that has long-term commercial implications. The potential commercial motivations for CDA's allegations are clear, and EPA must evaluate the CDA petition in that context.

CDA is asserting that EPA made a mistake when it decided to grant a FIFRA registration for EOS Surface. The CDA petition can be accurately characterized as an attack on the integrity of the FIFRA registration process. Cupron met every data and other requirement established by EPA for registration of EOS Surface as an antibacterial sanitizer. EPA's determination that these requirements were met was based on EPA's technical review of a series of scientific studies. The protocols for the studies on which EPA relied were reviewed and approved by EPA before the studies were initiated. Viewed in context, CDA is alleging that the EPA registration process was flawed, and such an allegation is wholly without any valid substantive basis.

The discussion below demonstrates that the allegations in the CDA petition have no sound theoretical or empirical basis. These allegations are also contradicted by a series of validated studies performed by an independent laboratory using standard protocols and in compliance with EPA OPP's Good Laboratory Practices (GLP) regulations in 40 C.F.R. Part 160. In short, nothing in the CDA petition provides any valid basis for issuance of a cancellation notice under FIFRA Section 6(b), 7 U.S.C. § 136d(b).

If there are any newly emerging scientific questions that EPA wishes to address by obtaining additional data concerning copper-containing antimicrobial surfaces (including EOS Surface as well as the registered copper alloy products), the appropriate vehicle to address these questions would be issuance of a Data Call-In (DCI) for all affected registrations pursuant to FIFRA Section 3(c)(2)(B), 7 U.S.C. § 136a(c)(2)(B). EPA recently has circulated for comment a draft protocol for a new type of study that EPA intends to address the long-term antimicrobial efficacy of copper-containing surfaces.[4] EPA announced simultaneously that it intends to issue a DCI requiring submission of such studies "at a later time."[5]

Cupron and EOS have submitted comments on the proposed protocol.[6] Cupron and EOS are not convinced that any additional data is needed to support the registration of EOS Surface, but intend to comply with any DCI that EPA elects to issue for a valid data need, presuming that any new data requirement is based on an appropriate protocol and is equitably imposed on all registrants of hard copper-containing antimicrobial surface products. Because Cupron and EOS believe that existing information is sufficient to establish the long-term antimicrobial efficacy of EOS Surface, they are confident that this efficacy would be confirmed by any future studies EPA may decide to require under FIFRA Section 3(c)(2)(B).

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4 OPP, "Protocol for the Evaluation of Bactericidal Activity of Hard, Non-Porous Copper/Copper-Alloy Surfaces," DRAFT (Sept. 9, 2014).

5 OPP, EPA Pesticide Program Updates, e-mail distribution (Oct. 2, 2014).

6 Message from Alastair B. Monk, Ph.D., Cupron, Inc., to Mark Perry, OPP (Nov. 14, 2014).

EPA's identification of additional data that it may require by a DCI, however, is a matter that should be resolved separately from disposition of the CDA petition. A decision that registrants of hard copper-containing antimicrobial surfaces should submit additional supporting data would provide no valid basis for cancelling, suspending, or even questioning the registration validly issued by EPA for EOS Surface, nor would it justify any delay in disposing of the CDA petition. If there are any actions by CDA or its members to publicize the pending petition, such actions would be commercially injurious to Cupron and EOS, and the potential for such commercial injury will only grow the longer the CDA petition remains pending. Because the CDA petition is without merit, it should be promptly and summarily denied. Prompt action by EPA will also mitigate the adverse commercial effects of the pending petition.

II. RESPONSE TO PETITION

A. Regulatory Background and Context for the Petition

1. The Antimicrobial Cupron Enhanced EOS Surface Was Registered Based on Scientifically Validated Tests Using EPA Approved Protocols, and CDA Has Not Suggested that Cupron Failed to Satisfy Any Data or Other Requirement Established by EPA

CDA is effectively alleging that EPA erred when it decided to grant a registration under FIFRA for EOS Surface. Viewed in context, CDA's contention that EPA should not have registered the product constitutes an attack on the integrity of the FIFRA registration process. Cupron met every requirement for registration established by EPA based on scientific data that were generated using EPA-approved protocols. The CDA petition is a commercially motivated

attack on the integrity of EPA's review of and reliance on scientific data. Moreover, as Cupron and EOS will show below, this attack is based on little more than conjecture.

EPA's decision to register EOS Surface was based on its careful review of a set of validated scientific tests demonstrating that the product met the EPA requirements for registration as a sanitizer. The protocols for the studies on which EPA relied in making this determination were reviewed and approved by EPA before the studies were initiated. In addition, EPA granted the registration of EOS Surface subject to a number of stringent conditions, and Cupron and EOS have satisfied each and every one of these conditions. In brief, Cupron and EOS satisfied all of the applicable data or other requirements for registration of an antibacterial sanitizer. CDA has not suggested, and could not legitimately suggest, otherwise. A brief review of the registration process for EOS Surface follows.

On February 10, 2010, Cupron and EOS submitted to EPA a proposed label for EOS Surface, and three protocols for studies to demonstrate the efficacy of the Antimicrobial Cupron Enhanced EOS Surface, as follows:

> HS01-Test Method for Efficacy of Cupron Enhanced Hard Surfaces as a Sanitizer
>
> HS02-Test Method for Continuous Reduction of Bacterial Contamination on Cupron Enhanced Hard Surfaces
>
> HS03-Test Method for Residual Self Sanitizing Activity of Cupron Enhanced Hard Surfaces

In protocol reviews for each of the three proposed studies issued on October 12, 2011, EPA stated that each submitted protocol was acceptable and that testing could proceed. EPA also

specifically confirmed that each study should utilize control carriers without the impregnated active ingredient, and that Cupron should submit a proposed stewardship program as part of the registration application.

On April 16, 2012, Cupron submitted a full registration application for EOS Surface, including GLP compliant efficacy studies based on the three approved protocols. Each test was conducted using multiple replicates from three separate manufacturing lots of EOS Surface, and control samples consisting of the polymeric surface without any impregnated active ingredient. The application included a proposed stewardship program along with all of the other information required by EPA.

On September 11, 2012, EPA granted a conditional registration for EOS Surface, including a requirement to implement a two-year stewardship program. During the subsequent two years, Cupron and EOS worked diligently to fulfill the conditions of registration.[7]

CDA does not allege in its submissions that any of the test data or other information submitted to EPA concerning EOS Surface failed to satisfy the EPA requirements for registration as an antibacterial sanitizer that were then in effect. Rather, CDA questions whether the registration requirements satisfied by Cupron and EOS were sufficient to allow EPA to determine whether EOS Surface would be an effective sanitizer in long-term use. Assertions

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[7] In addition to the mandatory stewardship program, Cupron and EOS have sponsored additional testing to confirm the efficacy of EOS Surface after actual use in the field, and to confirm efficacy across differing manufacturing lots. These studies are discussed below.

of this type are not a valid basis for a petition to cancel. Moreover, with the exception of a non-GLP study commissioned by CDA, these allegations are not based on any empirical information. Instead, CDA speculates that the testing accepted by EPA might be insufficient to support the allowed claims, and this speculation is based on little more than conjecture concerning the chemical composition and mechanism of action of EOS Surface.

2. The Appropriate Remedy for Any Hypothetical Deficiency in the Data Concerning the Long-Term Efficacy of Copper-Containing Antimicrobial Surfaces Is Issuance of a DCI Notice under FIFRA Section 3(c)(2)(B), Which Should Be Equally Applicable to Every Registered Copper-Containing Surface Product

Speculation that the nature or efficacy of a copper-containing antimicrobial surface might change over time is not limited to the polymeric matrix with cuprous oxide in EOS Surface. While CDA argues, without any credible evidence, that the cuprous oxide particles impregnated in the polymeric matrix of EOS Surface will be depleted over time in service, similar arguments could also be made concerning the potential effects of discoloration and oxidation, which alter the chemical composition of copper alloy surfaces and may therefore affect the long-term efficacy of copper alloy products. Thus, CDA's suggestion that the test protocols used to support registration of hard surface sanitizers may not adequately measure antimicrobial efficacy over a long period of service would apply to copper alloy products as well. If there are any emerging issues concerning long-term efficacy of the various registered copper-containing antimicrobial surfaces, the appropriate mechanism for EPA to use in addressing such issues is a DCI, not a petition to cancel.

In contrast, CDA claims that EPA should use its authority under FIFRA Section 6 to issue a formal adjudicatory notice of intent to cancel, and perhaps even a notice of intent to suspend, the FIFRA registration for EOS Surface.[8] Thus, CDA is proposing that EPA utilize its rarely used pesticide license revocation authority, which would require formal submissions to the FIFRA Scientific Advisory Panel and the U.S. Public Health Service, followed by an opportunity for one or more full-scale adjudicatory hearings, solely to single out one of the copper-containing antimicrobial surfaces for subsequent cancellation or suspension. This request for regulatory action is based primarily on CDA's unsupported view that EPA should have established more rigorous requirements before it registered this one particular product.

On its face, the new protocol that EPA circulated for comment on October 2, 2014, applies to all copper-containing hard surfaces, including copper alloy products. Thus, EPA clearly believes that if there is any need for additional data on long-term efficacy for this category of products, it is generic in nature. In these circumstances, CDA has not explained why copper alloy products should not also be subject to the proposed cancellation or suspension notices.

Although CDA requests that EPA undertake a formal license revocation process merely to remedy a purported deficiency in supporting data, FIFRA establishes a far more proportionate and less draconian procedure to be followed when EPA "determines that additional data are required to maintain in effect an existing registration of a pesticide." This is the DCI authority set forth in FIFRA Section 3(c)(2)(B). This provision in FIFRA implicitly recognizes

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[8] CDA Submission at 1, 9.

that scientific protocols and regulatory policies will evolve over time. EPA does not need to determine that it erred in granting a current registration in order to decide that it would be useful to collect additional data that can be used to evaluate whether a currently registered product continues to satisfy the standard for registration.

The approach advocated by CDA would also be unduly disruptive, by depriving users of an antimicrobial surface product that is intended to supplement, rather than to supplant, existing cleaning and disinfection practices. As mentioned above, the EOS Surface has been successfully deployed in a number of medical care and institutional settings, where it is being utilized in conjunction with standard disinfection practices to reduce transmission of dangerous pathogens. It is not reasonable or beneficial to public health interests to remove an appropriately registered and efficacious antimicrobial product from the marketplace based on speculative and unverified assertions by a competitor. To the extent that EPA determines that it would be useful to collect further data to address emerging questions, the legally correct and sensible solution is just what EPA apparently intends to do. In that event, EPA can decide to issue a DCI to obtain additional data that will supplement the data supporting the registrations for all copper-containing antimicrobial surface products. Based on the scientific data already available, as discussed below, Cupron and EOS are confident that any further testing EPA may decide to require will confirm the long-term efficacy of EOS Surface.

B. Specific Allegations in the CDA Petition

1. CDA's Argument that EOS Surface Changes Chemically over Time Is Speculative and without Any Empirical Basis

CDA argues that EOS Surface "changes chemically over time," and that the active copper ions will be "depleted" over the time that the material is in service.[9] This argument is wholly speculative. This conjecture by CDA is not supported by any empirical data demonstrating any alleged changes in the antimicrobial activity of EOS Surface,[10] or even by any quantitative or qualitative modeling of how these alleged changes might occur.

CDA's speculation concerning reductions in the efficacy of EOS Surface is not supported by the studies of continuous reduction of bacterial contamination and residual sanitizer activity that support the existing EOS Surface registration, which were conducted according to protocols that EPA reviewed and approved. Moreover, this speculation is also expressly contradicted by new data on the continued antimicrobial activity of samples of EOS Surface that have been in actual service for 18 months, which is discussed below.

In responding to these allegations, it is helpful to review basic information on the composition of EOS Surface and the active antibacterial agent that is incorporated in the product.

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9 CDA Submission at 2-3.

10 CDA submitted one study, but that study purports to demonstrate that EOS Surface is not even an effective sanitizer over a two-hour period. The technical deficiencies in and problems with this submission are discussed separately below.

The active ingredient in EOS Surface is cuprous oxide, also known as copper (I) oxide, which is a principal oxide of elemental copper. Cuprous oxide is a latticed structure mineral that can only be dissolved in ammonium hydroxide, aqueous ammonia and its salts, and concentrated acids. Cuprous oxide has a boiling point of 1,800°C and a melting point of 1,235°C. The mode of antibacterial activity for cuprous oxide (and also for other copper containing compounds) involves localized oxidation of the bacterial outer cell membrane. This oxidation process generates free radicals, and directly affects a range of cellular targets within the bacterial cell.

Cupron and EOS have previously provided information to EPA concerning the uniform distribution of cuprous oxide particles in the polymeric matrix of EOS Surface. The submitted information included SEM imaging of a cross section of the EOS Surface matrix clearly demonstrating the homogenous distribution of copper oxide particles throughout the matrix. As degradation of EOS Surface occurs over time, new polymeric material is exposed along with new cuprous oxide particles. There is no portion of the polymeric matrix of EOS Surface that can be exposed during gradual degradation in which cuprous oxide particles will not be exposed as well.

2. Although CDA Alleges that the Long-Term Efficacy of EOS Surface Has Not Been Demonstrated, a Study of Samples of EOS Surface that Were in Actual Service for 18 Months and Were Cleaned with Standard Hospital Disinfectants Found that EOS Surface Remains Fully Efficacious as a Sanitizer

CDA alleges that the long-term efficacy and durability of EOS Surface has not been demonstrated.[11] The key premise upon which CDA predicates its argument is that there is a finite supply of cuprous oxide in the polymeric matrix of EOS Surface that will be depleted while the material is in service, thereby resulting in reduction of the antimicrobial efficacy of the product. As noted above, this premise is not supported by any empirical data or by any modeling of the availability of cuprous oxide in the polymeric matrix. CDA argues that copper alloys containing 50 percent or less copper are not efficacious, but these materials are radically different in composition from EOS Surface, and no scientifically valid inference can be drawn from this comparison. CDA's comparison of EOS Surface to anti-fouling paint containing copper biocides is equally spurious.

In contrast to these speculative allegations unsupported by any data, Cupron and EOS have sponsored research in which an independent laboratory tested the continued antibacterial activity of samples of EOS Surface that were in actual service for 18 months at a hospital intensive care unit. Cupron and EOS decided to conduct this additional research as part of their ongoing product stewardship, prior to the time they were informed of the CDA petition. During the period that the tested samples were in service, they were cleaned on a daily basis with

[11] CDA Submission at 3-4.

disinfectants approved for use in that facility.[12] A GLP compliant study conducted for Cupron and EOS found that multiple replicates of EOS Surface removed from actual service remained efficacious as a sanitizer, controlling *Staphylococcus aureus* at a percent reduction exceeding 99.9%.[13] Thus, the supposition by CDA that EOS Surface will lose efficacy due to depletion of cuprous oxide from its surface is contradicted by test data from samples of EOS Surface that were in actual service at a health care facility for an 18-month period.

Similarly, the argument that the cuprous oxide in EOS Surface will be degraded or depleted by common cleaning agents is contradicted by the fact that the tested samples were cleaned on a daily basis using EPA approved disinfectants during the same 18-month period. In any case, any purported concern about the long-term durability of EOS Surface is of dubious relevance here unless it would affect the antimicrobial efficacy of the material. Since the active ingredient is distributed uniformly throughout the polymeric matrix, there is no reason to suppose that wear or abrasion would reduce efficacy. In addition, the previously submitted study of the residual self-sanitizing activity of EOS Surface expressly addressed the issue of wear and abrasion.

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12 Cupron is preparing, and will submit to EPA soon, an additional report that identifies the specific health care facility where the tested samples of EOS Surface were in service, specifies the cleaning and disinfection methods that were utilized on the tested samples while they were in service, and describes the chain of custody for collection of the tested samples and their subsequent delivery to the test laboratory.

13 Hollingsworth, A. L., Final Report, Efficacy Evaluation of Copper Enhanced Hard Surfaces as a Sanitizer, Test Agent: 18 Month Field Use Sample, Laboratory Project Identification Number 619-140 (Oct. 17, 2014), separately submitted to EPA on January 7, 2015, MRID Number _____.

In the face of actual scientific evidence, conjecture by CDA that EOS Surface will become ineffective over time must be rejected. Certainly there is no valid basis for EPA to consider cancellation of the product, even if EPA ultimately decides it would be appropriate to issue a DCI for additional supporting data.

3. CDA's Argument that Use of Wet Inoculation in Approved EPA Protocols Favors Copper-Containing Surfaces that Leach the Active Ingredient Is Both Speculative and Contrary to the Actual Test Conditions

CDA also argues that the standard EPA protocols for testing sanitizers are not appropriate for durable antimicrobial surfaces, because these protocols favor those surfaces that leach the active ingredient.[14] The implicit premise of this argument is that EOS Surface leaches the active ingredient, while copper alloy surfaces do not. This is a dubious premise, because the antimicrobial properties activity of both surfaces are dependent on the availability of copper ions, and there is no basis to suppose that the use of wet inoculation methods would not have a similar effect on the availability of copper ions from a copper alloy surface. In any case, the standard test methods allow drying time after the inoculation step, so these test methods also reflect the antibacterial efficacy of EOS Surface in dry conditions.

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[14] CDA Submission at 4-5.

4. Although CDA Alleges that Resistant Organisms May Develop Because EOS Surface Only Delivers a Sub-Lethal Dose, Actual Research Found No Evidence of Development of Any Resistant Subpopulation Even at a Lower Dose

CDA asserts that use of EOS Surface may promote resistant organisms, based on a supposition that exposed organisms will receive a sub-lethal dose, thereby promoting development of microbial resistance.[15] Like other speculative inferences by CDA, this is contradicted by data. Cupron previously published a study in a peer reviewed journal that assessed formation of resistant subpopulations after repeated exposure to the same active ingredient impregnated in a polymeric matrix at a lower concentration. This study found no evidence of development of any resistant subpopulation even after repeated bacterial insults.[16]

5. Although CDA Questions the Consistency of Product Chemistry across Different Manufacturing Lots, Product Stewardship Studies Demonstrate Consistent Efficacy as a Sanitizer in Three Independent Manufacturing Lots and Multiple Replicates from Each Lot

CDA questions the consistency of product chemistry for EOS Surface across differing manufacturing lots, and the effect of the fabrication step on the efficacy of the finished product.[17] Like its other allegations, CDA has no information or data that would establish any basis for these concerns.

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15 CDA Submission at 5-6.

16 Borkow, G., Okon-Levy, N., and Gabbay, J. , Copper oxide impregnated wound dressing: biocidal and safety studies. *Wounds* 22: 301-310 (2010).

17 CDA Submission at 6.

With respect to product variability over differing manufacturing lots, Cupron and EOS have generated actual data as part of product stewardship that shows that differing lots of EOS Surface are equally efficacious. GLP compliant studies conducted for Cupron and EOS at an independent laboratory evaluated the antimicrobial efficacy of multiple replicates of three manufacturing lots of EOS Surface (beige)[18] and three manufacturing lots of EOS Surface (grey).[19] In each instance, the study demonstrated that every replicate for every manufacturing lot was an effective sanitizer, with a control level exceeding 99.9% for *Staphylococcus aureus* and *Enterobacter aerogenes.*

With respect to the allegation by CDA that the product preparation done by fabricators may affect the efficacy of the finished EOS Surface, there is no basis for this supposition. The finishing step does not and cannot alter the uniform distribution of the pesticidal active ingredient throughout the polymeric matrix of the entire product. Moreover, given the high melting point of cuprous oxide, any heat generated during the finishing process will have no effect on the particles of active ingredient impregnated in the polymeric matrix.

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[18] Hollingsworth, A. L., Final Report, Efficacy Evaluation of Copper Enhanced Hard Surfaces as a Sanitizer, Test Agent: Antimicrobial Cupron Enhanced EOS Surface (Beige), Laboratory Project Identification Number 619-138 (Oct. 15, 2014), separately submitted to EPA on January 7, 2015, MRID Number _____.

[19] Hollingsworth, A. L., Final Report, Efficacy Evaluation of Copper Enhanced Hard Surfaces as a Sanitizer, Test Agent: Antimicrobial Cupron Enhanced EOS Surface (Grey), Laboratory Project Identification Number 619-139 (Oct. 15, 2014), separately submitted to EPA on January 7, 2015, MRID Number _____.

CDA also purports to cite the "EOS fabrication manual." The document that is linked in the CDA submission, however, is not the correct fabrication manual for the registered EOS Surface product.

6. CDA's Allegation that There Is a Disconnect between the Directions for Use and Functioning of EOS Surface Incorrectly Conflates the Issue of a Barrier if the User Coats the Product and the Availability of Copper from the Polymeric Matrix

CDA asserts that there is some sort of "disconnect" between the directions for use that state that the product should not be coated by the user and the intrinsic nature of EOS Surface.[20] Frankly, Cupron and EOS find this argument to be incoherent. There is no reason to suggest that the introduction by the user of a physical barrier to availability of the active ingredient is related to the potential availability of active ingredient that is embedded in the polymeric matrix. At best, this argument is just a variant on the general notion that copper ions will be depleted and the efficacy will decline over time, an argument that is contradicted by actual data.

7. CDA Incorrectly Cites Cleaning Instructions on the Cupron Website that Concern a Different Product, and Also Cites Statements in a Newspaper Article Concerning EOS Surface that Was Not Written by Cupron

CDA also argues that the cleaning instructions on the Cupron website are contrary to label directions, and that an article referenced on the Cupron website makes inappropriate

[20] CDA Submission at 7.

claims.[21] Before addressing these allegations, it should be pointed out that, even if there was any substance to them (which there is not), such allegations would have no discernible relevance to a petition to cancel or to suspend the registration for EOS Surface. In any case, like so many other assertions by CDA, these assertions are misleading.

The cleaning instructions cited by CDA are for an entirely different EOS product line, as should have been apparent from the word "residential" that is included in the web URL referenced by CDA. The correct cleaning instructions for the registered Cupron/EOS product that is the subject of the CDA petition are included in a different website (www.eoscu.com) that was expressly built for that product, and all materials in that website are entirely consistent with the approved registration for that product.

CDA also refers to an article referenced on the EOS/Cupron website that refers to EOS Surface as an item "that essentially cleans itself." This colloquial description of the nature of the product appears in a newspaper article published in the Richmond Times Dispatch, and it is neither fair nor appropriate to attribute statements made in such a press account to Cupron or to EOS. Nevertheless, to avoid any incorrect impression, Cupron and EOS have decided to remove the link to this newspaper article from their website.

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[21] CDA Submission at 7-8.

8. CDA's Argument that the Registration Should Be Specific to Countertops Has No Empirical or Theoretical Basis, and Is Equally Applicable to Copper Alloy Surfaces

CDA argues that the registration for EOS Surface should be limited to countertops because there is no assurance that the composition of the material will not vary depending on the form in which it is sold, and because there may be differences in antimicrobial performance based on the form of the material.[22] During the registration process, Cupron and EOS provided to EPA a description of the production process for EOS Surface, which assures that particles of cuprous oxide are uniformly distributed throughout the entire polymeric matrix.[23] This uniform composition is not altered when the polymeric matrix is shaped or formed for different end uses, because the amenable nature of thermoplastic polymers allows the material to be worked easily into a range of form factors. CDA argues that copper alloy products are different from the EOS Surface because they must all meet general industry specifications, but this argument has no foundation. All EOS Surface products that are sold, regardless of form factor, must conform to the composition information provided to EPA as part of the registration process for the product.

There is no plausible reason to suppose that the antimicrobial efficacy of a polymeric matrix of uniform composition would differ depending on the form factor. Testing every form factor that is sold for antibacterial efficacy would be scientifically unjustified, and such a policy would require significant expenditures on the development and implementation of

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22 CDA Submission at 8.

23 The details of the manufacturing process for EOS Surface are Confidential Business Information and will not be restated in this submission.

new testing protocols. If EPA were to determine that there is some valid reason to require separate testing for any other form factor, it is likely that the rationale for such testing would apply with equal force to copper alloy products. In any event, any data needs based on newly identified questions can be appropriately addressed through the DCI process, and are not a proper basis for a petition to cancel

C. Deficiencies in the Study Submitted by CDA

1. The CDA Study Is a Non-GLP Study Based on a Protocol Devised by the Contractor and Not Approved by EPA OPP

On May 28, 2013, CDA supplemented its initial submission with a study that purports to show that samples of EOS Surface were not efficacious in controlling *Staphylococcus aereus* to the minimum level of control required for a registered sanitizer.[24] It does not appear that this study was intended to evaluate CDA's speculative assertions concerning long-term efficacy of EOS Surface. Rather, the study tested short-term efficacy, and the reported results cannot be readily reconciled with the validated scientific studies that support registration of EOS Surface, or with the additional scientific studies submitted by Cupron on January 7, 2015.

At the direction of CDA, the CDA Study was not conducted in conformity to GLP requirements.[25] The reasons why CDA gave this direction to the laboratory that conducted the

[24] CDA Study at 5.

[25] CDA Study at 3.

study are not stated. Perhaps the laboratory determined that it could not conduct a GLP compliant study within the parameters specified by CDA. The study was also not conducted according to the standard EPA OPP protocol for sanitizer efficacy, and the alternative protocol that was used (CSC02021213.CNFS) has not been provided. There is also no indication that this alternative protocol was submitted to EPA for prior review or approval.

2. There Is No Documented Chain of Custody for the Test Material in the CDA Study, and Cupron Cannot Confirm the Origin of the Samples that Were Purportedly Tested

The CDA Study provides no information concerning the chain of custody for the samples of EOS Surface that were purportedly tested. In addition, the CDA Study does not identify the nature or origin of the control samples that were used in the test. No material lot numbers for any sample have been recorded.

After extensive internal review, Cupron and EOS could find no reference to a request for samples from CDA and cannot verify the origin of the samples of EOS Surface that were purportedly used in this study. Cupron and EOS cannot determine from the study report whether the tested samples were actual registered EOS Surface product, and the possibility cannot be excluded that CDA tested color matching samples that are sometimes supplied to architects solely for aesthetic purposes.

In addition, Cupron and EOS have not manufactured any samples of the EOS Surface polymer without the impregnated cuprous oxide for release to the public, nor have they

received any request from any external party for such samples. As explained above, EPA required use of control carriers without the impregnated active ingredient as an essential element in the tests that support registration of EOS Surface.

These serious deficiencies in the chain of custody and sample documentation for the CDA Study further undermine the reported results. Cupron and EOS cannot verify the authenticity, or determine the prior history, of any sample that was used in this study.

3. The CDA Study Cannot Be Reconciled with the Studies that Were Originally Submitted to Support Registration of EOS Surface, or with the Other Efficacy Studies Just Submitted to EPA

The CDA Study reports results concerning the short-term efficacy of EOS Surface that cannot be reconciled with validated scientific studies that support registration of EOS Surface, or with any of the new studies submitted by Cupron on January 7, 2015. The CDA Study is not GLP compliant. The CDA Study was not conducted in accordance with a standard or approved protocol, and it includes no chain of custody or verifiable history concerning any of the samples tested.

These are all serious deficiencies that materially undermine the credibility of the test results. The CDA Study should be assigned no weight to the degree that it contravenes validated test results obtained in a series of GLP compliant studies that have none of these serious deficiencies.

D. EPA Processing of This Petition

1. The Administrative Procedure that EPA Selected Is Likely to Be Commercially Injurious to Cupron and EOS, and the Potential for Commercial Injury Will Be Compounded the Longer the Petition Remains Pending

Cupron and EOS were not aware of CDA's November 2, 2012, and May 28, 2013, submissions until Cupron received Mr. Hebert's September 25, 2014, letter. Had EPA informally requested any information from Cupron or EOS to help evaluate the credibility of these submissions during the intervening period, Cupron and EOS would have been pleased to cooperate in any inquiry. Nevertheless, now that EPA has decided to characterize these submissions by CDA as a petition to cancel, and has established formal procedures governing the form and submission of this response,[26] Cupron and EOS are concerned that customers might construe this process as an indication that EPA attaches credibility to or even endorses the CDA allegations. Unfortunately, there is nothing in the formal process established by EPA that will prevent CDA members from encouraging such misapprehensions, and there is an incentive for CDA members to do so because they will thereby gain a competitive advantage.

CDA has a commercial interest in this petition because CDA members are in direct competition with Cupron and EOS in the market for copper-based durable antimicrobial

[26] In a letter dated November 5, 2014, Cupron and EOS requested that EPA relax the formal procedures it established for processing the CDA petition, which are not legally required and are potentially prejudicial to Cupron and EOS. CDA counsel submitted an opposition to that request on November 7, 2014. At this time, EPA has not acted either to grant or to deny the request by Cupron and EOS.

surfaces. A decision by any prospective customer to select a particular antimicrobial surface product has quite significant commercial implications because of the durable nature of each product and the protracted period it will be in service. The longer that EPA takes to dispose of the CDA petition, the greater the potential for irreparable commercial effects on Cupron. EPA should recognize the potential for grave commercial injury that is inherent in the process for responding to the CDA submissions it has chosen, and EPA should make all reasonable efforts to mitigate that potential injury.

2. If EPA Decides that Cancellation Is Not Warranted, EPA Can and Should Deny the CDA Petition Promptly, before EPA Makes a Decision Whether to Issue a DCI for New Data Concerning the Long-Term Efficacy of Copper-Containing Surfaces

If EPA decides that the CDA petition does not warrant issuance of a cancellation or suspension notice, EPA should deny the petition promptly. The prejudicial effect of the petition process on Cupron and EOS will be exacerbated by delay. EPA should be mindful of the adverse competitive effect of this commercially motivated petition to cancel, and should not allow CDA to manipulate the administrative process in a manner that damages Cupron and EOS. By acting promptly to dispose of the petition, EPA can mitigate the risk of commercial injury to Cupron and EOS.

There is no reason to defer action on the CDA petition while EPA evaluates the need for a supplementary DCI. The complexity of the scientific issues addressed by the draft protocol on which EPA has solicited comment, and the protracted delays that can be associated with the DCI process itself, suggest the possibility of a significant delay. EPA has stated only

that it expects to issue a DCI "at a later time." EPA should separate its decision concerning the CDA petition from preparation and issuance of the forthcoming DCI. When EPA denies the CDA petition, it can reference any other forthcoming actions it may deem pertinent to that denial action.

3. Because Speculative Questions Concerning Long-Term Efficacy Are At Least as Plausible for Copper Alloy Surfaces, Cupron Is Considering Whether It Should File a Petition to Cancel for Copper Alloy Products

Cupron and EOS may reluctantly have to consider whether any additional actions are needed. Cupron and EOS believe that EOS Surface was properly registered, in appropriate reliance on the data that EPA required at that time to support registration. Nonetheless, there are unresolved issues concerning the long-term efficacy of copper alloy surfaces registered by CDA members that are at least as significant as the questions posed by CDA. Accordingly, it may be appropriate and proportionate for Cupron and EOS to identify unresolved concerns regarding the long-term durability and efficacy of copper alloy surfaces in a separate petition to cancel the copper alloy products.

III. CONCLUSION

For all of the reasons stated above, EPA should determine that the CDA petition to cancel or to suspend EOS Surface is without merit, and EPA should promptly issue a decision denying that petition.

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